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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,790	05/24/2000	Antonio Moroni	498-206	4530

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/14/2004

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,790

Applicant(s)

MORONI, ANTONIO

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-15 and 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6,8-15,19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, line 5, the fabric comprises "polymeric filaments" and then in line 8, the fabric comprises "drawn polymeric yarns". It is not clear if this is a multiple component fabric. Did applicant mean to recite said filaments? Additionally, claim 11 recites "a plurality of yarns" in line 5 and then further recites the fabric having "drawn polymeric yarns" in line 9. Are these the same yarns? The other claims are indefinite for depending from these claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6,8-15,17,19,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuwahara (WO 99/04727) in view of Stinson (5980564). See US 6346119 for translation. Fig. 2 shows a stent-graft with a tubular fabric **13** and a deformable stent **14**. Kuwahara et al. disclose the graft tube is made of a woven fabric having a plurality of fibers, col. 3, lines 1-3. The graft tube is fully capable of being used

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as a vascular, endovascular or intraluminal prosthesis. Kuwahara also discloses the polyester fibers can be made of polyethylene naphthalate (PEN), col. 4, lines 45-49.

With respect to claim 8, the prosthesis can have a coating, col. 4, lines 65-67.

Regarding claim 9, the fabric can have about 20-100 filaments, col. 4, lines 59-64. With respect to claim 10, Kuwahara additionally discloses the filaments have a denier of 50 and 100 denier for the circumferential drawn yarns or filaments, col. 6, lines 63-66. The examiner asserts that the claimed physical properties and formula (in this case, the material being radiation resistant and hydrolytically stable) are present in the Kuwahara material to some extent even though they are not explicitly recited. All materials can be considered radiation resistant, since they are inherently exposed to some sort of radiation, such as radio waves, visible radiation from lights, etc. or possibly UV radiation. Since there is no objective or quantitative measurements as to ascertain what is considered "radiation resistant" or "hydrolytically stable" the properties are inherently possessed by the prior art material. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. The fabric is inherently stable at least *about* 120°C because this temperature is well below the melting point of PEN, which is 270°C. However, Kuwahara et al. does not explicitly disclose the filaments are drawn. Stinson teaches stent-grafts are made from filaments, col. 6, lines 44-47. Stinson also teaches the filaments are strengthened by drawing at a lower temperature, col. 4, lines 42,43. It would have been obvious to one of ordinary skill in the art to draw the filaments at the lower temperature as taught by Stinson for the

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fabric of Kuwahara et al. in order to increase the filament strength. Drawing filaments or yarns to form a fabric is well known in the art.

Claims 18,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuwahara (WO 99/04727) in view of Schmitt (5443499) and Vanney et al. (5876436). Kuwahara is explained supra. However, Kuwahara does not disclose drawn polymeric filaments, i.e. drawing filaments to a point just prior to the fracture point or producing the prosthesis under steam sterilization. Schmitt teaches drawing yarns to a point prior to the fracture point to increase the tensile strength and decrease the elongation to failure, col. 4, lines 14-16. Vanney et al. teach that a fabric prosthesis is steam sterilized, col. 8, lines 1-7. It would have been obvious to one of ordinary skill in the art to use steam sterilization on a fabric prosthesis as taught by Vanney et al. and to draw the filaments as taught by Stinson with a stent graft of Kuwahara in order to provide a safe, stronger and sterile implant for the patient. It is well known in the surgical art that prostheses should be sterile for implantation in order to reduce any risk of bacterial infection. Regarding claim 20, it would have been obvious to one of ordinary skill in the art to use the teaching of Schmitt to draw yarns just prior to the fracture point with the implantable prosthesis of Kuwahara as modified by Schmitt and Vanney to increase its tensile strength.

Response to Arguments

Applicant's arguments with respect to claims 1,11,17,18 have been considered but are moot in view of the new ground(s) of rejection. In response to Applicant's remarks that the Kuwahara reference does not inherently possess the claimed properties, it must be noted that the applicant has not proven that the properties are not present, but only disputed this. It should also be noted that Kuwahara was interested in using stable polymeric yarns and thus it can be construed that Kuwahara's PEN is stable, see col. 4, lines 50-52.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738



Paul Prebilic

Primary Examiner

